Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 90-114, 116-121, 124-133 and 136-140 are pending in the application, with claims 90, 98, 106, 114, 121 and 133 being the independent claims. Support for the inclusion of "lactose binding activity" can be found, for example, on page 16, line 21 to page 17, line 14 of the written description; and in originally filed claims 121, 122, 133 and 134. These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejections under 35 U.S.C. § 101

The Advisory Action mailed on January 29, 2002 maintained the rejection of claims 90-114, 116-121, 124-133 and 136-140 under 35 U.S.C. § 101 for lack of utility. File Wrapper Paper No. 19, page 2. The Examiner indicated that Applicants' arguments in support of utility were found to be unpersuasive. *Id.*

Part of the basis of this finding was that "one of skill in the art would use ecalectin to raise antibodies that bind to ecalectin and the Galectin-9 of Tureci (which is not the Galectin 9 of the instant specification) . . . not as asserted by applicant, SEQ ID NO:4 which contains extraneous amino acids not found in ecalectin or the Galectin-9 of

Tureci." File Wrapper Paper No. 19, page 2. It is respectfully pointed out to the Examiner that ecalectin and Galectin-9 of Tureci contain the additional amino acids, *and not* Applicants' galectin 9[1]. Explanation of this discrepancy was previously given in greater detail and can be found in pages 11-12 of the Amendment and Reply Under 37 C.F.R. § 1.111, filed on June 15, 2001.

Moreover, Applicants have directed the Examiner to the references of Exhibits D, E, F, I and J to show that their assertion of utility is specific, substantial and credible. Exhibits filed June 15 and December 14, 2001. Applicants asserted that their SEQ ID NO:4, which is highly homologous to ecalectin and galectin 9 of Tureci (both described by the Exhibits), can be used for the purpose of raising antibodies to detect asthma or Hodgkin's disease. Such an assertion is specific because i) it is a detection of particular diseases and ii) not all proteins can be used to detect these diseases. Such an assertion is substantial because the detection of these diseases is a medical benefit immediately realized by society. Such an assertion is credible because of the high degree of sequence homology present and the recognized relationship between these proteins and these diseases.

Another basis of the rejection is "that ecalectin or Galectin-9 of Tureci function . . . [as] part of a general immune response caused by T-cell mediated inflammatory reactions in humans and not specifically confined to asthma or Hodgkin's disease." File Wrapper Paper No. 19, page 2. Furthermore, the Examiner states that "[t]he art of record provides no support for a method wherein the detection of the Galcetin-9 of Tureci or

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[1] Ecalectin and Tureci's galectin-9 are likely to be the same protein. *See* Exhibit I, page 7, filed December 14, 2001.

ecalectin would be diagnostic for Hodgkin's disease or asthma." *Id.* at 3. Applicants respectfully disagree.

In contrast with the Examiner's allegations, the previously submitted exhibits support the assertion that these proteins are not merely part of a general immune response. Moreover, they have been used diagnostically for Hodgkin's disease. For example, Tureci *et al.* stated that "antibodies reactive with human galectin-9 were detected in about 50% of the sera derived from patients with Hodgkin's disease, but not in the sera of healthy individuals or patients suffering from other tumors . . . suggesting that the antibodies might have been generated as a tumor-specific response." *See* Exhibit F, page 6421, filed June 15, 2001. Regarding asthma, Matsumoto *et al.* have shown a marked increase in ecalectin transcript (~50 to ~90 fold increase) when allergic patients are exposed to an allergen. *See* Exhibit D, page 16978, filed June 15, 2001. Moreover, ecalectin has been implicated in asthma. *See* Exhibit I, page 8, filed December 14, 2001. Thus, ecalectin and galectin 9 of Tureci are specific for both Hodgkin's disease and asthma.

Another basis of the rejection is that "neither the specification nor any art of record has described SEQ ID NO:4 as having chemokine properties or as being overexpressed in Hodgkin's disease or asthma. . . . Further, the specification provides no molecular mechanism of action of SEQ ID NO:4 to provide a nexus to a disease state involving eosinophiles [*sic*, eosinophils]." File Wrapper Paper No. 19, page 3. Applicant respectfully traverses that this could be a proper basis for a rejection.

As previously argued by Applicant, biological or chemical explanations of how or why SEQ ID NO:4 plays a role in asthma and/or Hodgkin's disease are not necessary to

support utility. Rather, "as the courts have repeatedly held, all that is required is a reasonable correlation between the activity and the asserted use." M.P.E.P. (Eighth) § 2107.03 (I) (2001) (*citing Nelson v. Bowler,* 206 U.S.P.Q. 881, 884 (CCPA 1980)). Here, Applicants have already shown that the activity of SEQ ID NO:4 is implicated in asthma and/or Hodgkin's disease based on its homology to ecalectin and the galectin 9 of Tureci referenced in the various exhibits. Moreover, this activity is reasonably correlated to the assertion that Applicants' galectin 9 is useful to raise antibodies with which to diagnose these diseases.

Based on the aforementioned arguments, Applicants respectfully request that the Examiner reconsider and withdraw the rejection under 35 U.S.C. § 101 of claims 90-114, 116-121, 124-133 and 136-140 for lack of utility.

Rejections under 35 U.S.C. § 112

The Advisory Action mailed on January 29, 2002 maintained the rejection of claims 90, 92, 94-98, 100 and 102-114, 116-121, 124-133 and 136-140 under 35 U.S.C. § 112. File Wrapper Paper No. 19, page 2. In particular, the Examiner has rejected these claims on the ground that the written description does not enable these claims. Applicant respectfully reminds the Examiner that claims 91, 93, 99 and 101 have not previously w/d been rejected under 35 U.S.C. § 112, nor have reasons for their rejection been provided in the Advisory Action.

Applicants have amended independent claims 90, 98, 106, 114, 121 and 133 to include a recitation of lactose binding activity. It is believed that such a recitation renders the enablement rejection under 35 U.S.C. § 112 moot. Accordingly, Applicants

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respectfully request that the Examiner reconsider and withdraw the § 112 rejection of claims 90, 92, 94-98, 100 and 102-114, 116-121, 124-133 and 136-140.

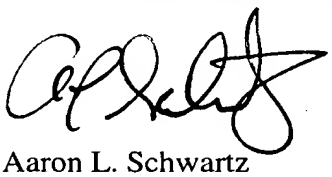
Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



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Version with markings to show changes made

90. (amended) An isolated protein comprising an amino acid sequence at least 95% identical to amino acids 2 to 311 in SEQ ID NO:4, wherein said protein has lactose binding activity.

98. (amended) An isolated protein comprising an amino acid sequence at least 95% identical to the mature amino acid sequence encoded by the cDNA clone contained in ATCC Deposit No. 97733, wherein said protein has lactose binding activity.

106. (amended) An isolated protein comprising an amino acid sequence selected from the group consisting of:

(a) amino acids 62 to 102 in SEQ ID NO:4;

(b) amino acids 226 to 259 in SEQ ID NO:4; and

(c) amino acids 197 to 308 in SEQ ID NO:4;

wherein said protein has lactose binding activity.

114. (twice amended) An isolated protein comprising 30 contiguous amino acids of SEQ ID NO:4, wherein said protein has lactose binding activity.

121. (twice amended) An isolated protein comprising a fragment of the amino acid sequence of SEQ ID NO:4;

wherein said protein [specifically binds an antibody that specifically binds a protein consisting of the complete amino acid sequence of SEQ ID NO:4] has lactose binding activity.

Claim 133. (thrice amended) An isolated protein comprising amino acid residues encoded by a polynucleotide which hybridizes to the polynucleotide complement of the coding region of SEQ ID NO:3 under the following conditions:

(a) incubating overnight at 42°C in a solution consisting of 50% formamide, 5x SSC, 50 mM sodium phosphate (pH 7.6), 5x Denhardt's solution, 10% dextran sulfate, and 20 μg/ml denatured, sheared salmon sperm DNA; and

(b) washing at 65°C in a solution consisting of 0.1x SSC;

wherein said [polynucleotide encodes a protein that specifically binds an antibody that specifically binds a polypeptide consisting of the complete amino acid sequence of SEQ ID NO:4] protein has lactose binding activity.